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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/732,782                       | 12/10/2003  | Stephen Hsu          | 275.0007 0101       | 6883             |
| 26813                            | 7590        | 07/07/2006           | EXAMINER            |                  |
| MUETING, RAASCH & GEBHARDT, P.A. |             |                      | JOYCE, CATHERINE    |                  |
| P.O. BOX 581415                  |             |                      | ART UNIT            |                  |
| MINNEAPOLIS, MN 55458            |             |                      | PAPER NUMBER        |                  |

1642

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                   |  |
|------------------------------|---------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/732,782  | <b>Applicant(s)</b><br>HSU ET AL. |  |
|                              | <b>Examiner</b><br>Catherine M. Joyce | <b>Art Unit</b><br>1642           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12,17,25,26 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12,17,25,26 and 33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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#### DETAILED ACTION

1. The Amendment filed April 25, 2006 in response to the Office Action of January 31, 2006 is acknowledged and has been entered. Claims 13-16, 18-24, 27-32, 34-35 have been canceled, and claims 1-12, 17, 25-26, and 33 are pending. Upon review and reconsideration, and in view of the amendment of the claims, the restriction requirement set forth in the Office Action mailed October 19, 2005 is withdrawn and the following restriction requirement is set forth.

#### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim 1, as drawn to a method of determining if cancer cells are resistant to an agent comprising comparing the level of p57/KIP2 level in the cancer cells after contact with the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent, classified in class 435, subclass 4.
  - II. Claim 8, as drawn to a method of determining if cancer cells are sensitive to an agent comprising comparing the level of p57/KIP2 level in the cancer cells after contact with the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent, classified in class 435, subclass 4.
  - III. Claim 8, as drawn to a method of identifying an agent effective for the treatment of a cancer comprising comparing the level of p57/KIP2 level in the cancer cells after contact with the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent, classified in class 435, subclass 4.
  - IV. Claims 2-7, 10, 11, 17, 25-26, and 33, as drawn to a method of determining the therapeutic effectiveness of an agent comprising comparing the level of p57/KIP2 level in the cancer cells after contact with

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the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent, classified in class 435, subclass 4.

- V. Claim 12, as drawn to a of optimizing the formulation of an agent for the treatment of a cancer comprising comparing the level of p57/KIP2 level in cancer cells after contact with a first formulation or a second formulation of the agent, the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent, classified in class 435, subclass 4.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of Groups I to V are materially distinct methods which differ at least in method steps. While the searches for the inventions of Groups I to V would be overlapping, they would not be coextensive. Thus, searching any of groups I-V together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Further, the above election of species are required

If any of Groups I-V are elected, the election of specific method of determining the level of p57/KIP2 from the following list is required: detecting the p57/KIP2 protein; detecting the p57/KIP2 protein; detecting mRNA encoding p57/KIP2.

If Group IV is elected, the election of a specific cancer cell type is required from the following list: an oral cancer, an esophageal cancer, a gastric cancer, colorectal cancer, a prostate cancer, a bladder cancer, a skin cancer, a cervical cancer, a breast cancer.

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If Group IV is elected, the election of specific normal cell type from the following list is required: primary epidermal keratinocytes; fibroblasts.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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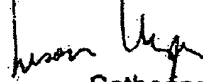
10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER



Catherine M. Joyce  
Examiner  
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